SIU 7398
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent of: Kathleen C. M. Campbell
Patent No.: 7,557,142 B2
Issued: July 7, 2009
Confirmation No.: 8896
For: THERAPEUTIC USE OF METHIONINE TO REDUCE THE TOXICITY OF PLATINUM-CONTAINING ANTI-TUMOR COMPOUNDS

March 9, 2010

REQUEST FOR EXPEDITED ISSUANCE OF CERTIFICATE OF CORRECTION UNDER 37 CFR 1.322

TO THE DIRECTOR OF THE UNITES STATES PATENT AND TRADEMARK OFFICE,

SIR:

On studying the above-identified patent, the following errors, apparently made by the Patent and Trademark Office, were found (these errors are also noted on the attached form PTO/SB/44):

Column 28, Claim 1, Line 41: "or a pharmaceutically" should read -- or pharmaceutically --.

REMARKS

In accordance with 37 CFR 1.322, a copy of Amendment G, dated January 11, 2009, and a copy of the Notice of Allowance dated March 2, 2009, are attached.

We respectfully request that a certificate of correction be issued.

Respectfully submitted,

Janet S. Hendrickson, Ph.D., Reg. No. 55,258
SENNIGER POWERS LLP
100 North Broadway, 17th Floor
St. Louis, Missouri 63102
(314) 231-5400

JSH/clp
*Enclosures

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Kathleen C.M. Campbell Art Unit: 1614
Serial No.: 10/694,448
Filed: October 27, 2003
Confirmation No.: 8896
For: THERAPEUTIC USE OF METHIONINE TO REDUCE THE TOXICITY OF PLATINUM-CONTAINING ANTI-TUMOR COMPOUNDS
Examiner: James D. Anderson

January 11, 2009

AMENDMENT G

TO THE ASSISTANT COMMISSIONER FOR PATENTS,

SIR:

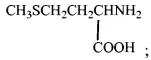
In response to the Office action dated November 10, 2008, please enter this response.

A **listing of claims** begins on page 2 of this paper.

Remarks begin on page 7 of this paper.

IN THE CLAIMS:

1. (Previously Presented) A method for reducing the incidence of ototoxicity in a patient selected from the group consisting of a human, a cat, and a dog undergoing treatment with a chemotherapeutic effective amount of an anti-tumor platinum-coordination compound, the method comprising administering to said patient an effective amount of an otoprotective agent comprising methionine having the structure



or a pharmaceutically acceptable salt thereof.

2. (Cancelled)

3. (Previously Presented) The method of claim 1, wherein said otoprotective agent is selected from the group consisting of L-methionine, a mixture of D-methionine and L-methionine, and a combination thereof.

4. (Previously Presented) The method of claim 1, wherein said otoprotective agent comprises L-methionine.

5. (Previously Presented) The method of claim 1, wherein said otoprotective agent comprises a mixture of D-methionine and L-methionine.

6. (Canceled)

7. (Original) The method of claim 1, wherein said otoprotective agent is administered prior to the administration of said anti-tumor platinum-coordination compound.

8. (Original) The method of claim 1, wherein said otoprotective agent is administered simultaneously with the administration of said anti-tumor platinum-coordination compound.

9. (Original) The method of claim 1, wherein said otoprotective agent is administered subsequently to administration of said anti-tumor platinum-coordination compound.

10. (Original) The method of claim 1, wherein said effective amount of said otoprotective agent is administered to said patient in a time period from about 36 hours before administration of said anti-tumor platinum-coordination compound to about 36 hours after administration of said anti-tumor platinum-coordination compound.

11. (Original) The method of claim 1, wherein said effective amount of said otoprotective agent is administered to said patient in a time period from about 25 hours before administration of said anti-tumor platinum-coordination compound to about 25 hours after administration of said anti-tumor platinum-coordination compound.

12. (Original) The method of claim 1, wherein said effective amount of said otoprotective agent is administered to said patient in a time period from about 6 hours before administration of said anti-tumor platinum-coordination compound to about 6 hours after administration of said anti-tumor platinum-coordination compound.

13. (Original) The method of claim 1, wherein said effective amount of said otoprotective agent is administered to said patient in a time period from about 1 hour before administration of said anti-tumor platinum-coordination compound to about 1 hour after administration of said anti-tumor platinum-coordination compound.

14. (Original) The method of claim 1, wherein said effective amount of said otoprotective agent is administered to said patient in a time period from about one-half hour before administration of said anti-tumor platinum-coordination compound to about one-half hour after administration of said anti-tumor platinum-coordination compound.

15. (Previously Presented) The method of claim 1, wherein said anti-tumor platinum-coordination compound is selected from the group consisting of *cis*-diaminedi-chloroplatinum(II), *trans*-diaminodichloroplatinum(II), *cis*-diamine-diaquaplatinum(II)-ion,

chloro(diethyl-enetriamine)-platinum(II) chloride, dichloro(ethylene-diamine)-platinum(II), diamine(1,1-cyclobutanedi-carboxylato)-platinum(II), spiroplatin, dichlorotrans-dihydroxybisisopropolamine platinum IV (iproplatin), diamine(2-ethylmalonato)-platinum(II), ethylenediamine-malonatoplatinum(II), aqua(1,2-diaminodyclohexane)-sulfatoplatinum(II), (1,2-diaminocyclohexane)malonato-platinum(II), (4-carboxy-phthalato)(1,2-diaminocyclo-hexane)-platinum(II), (1,2-diaminocyclohexane)-(isocitrato)platinum(II), (1,2-diaminocyclohexane)-*cis*(pyruvato)platinum(II), and (1,2-diaminocyclohexane)-oxalatoplatinum(II).

16. (Previously Presented) The method of claim 15, wherein said anti-tumor platinum-coordination compound comprises *cis*-diaminedichloro-platinum(II).

17. (Original) The method of claim 1, wherein said anti-tumor platinum-coordination compound is selected from the group consisting of cisplatin, carboplatin and iproplatin.

18. (Currently Amended) The method of claim 1, wherein said otoprotective agent is administered parenterally, orally, or topically to the round window membrane of said patient.

19. (Original) The method of claim 18, wherein the administration of said effective amount of said otoprotective agent results in a blood serum level equivalent to that achieved by parenteral administration in the range of from about 0.1 mg/kg body weight to about 500 mg/kg body weight.

20. (Original) The method of claim 18, wherein the administration of said effective amount of said otoprotective agent results in a blood serum level equivalent to that achieved by parenteral administration in the range of from about 1 mg/kg body weight to about 400 mg/kg body weight.

21. (Original) The method of claim 18, wherein the administration of said effective amount of said otoprotective agent results in a blood serum level equivalent to that achieved by parenteral administration in the range of from about 10 mg/kg body weight to about 300 mg/kg body weight.

22. (Original) The method of claim 18, wherein the administration of said effective amount of said otoprotective agent results in a blood serum level equivalent to that achieved by parenteral administration in the range of from about 10 mg/kg body weight to about 75 mg/kg body weight.

23. (Original) The method of claim 1, wherein the molar ratio of the effective amount of said otoprotective agent to the effective amount of said anti-tumor platinum-coordination compound is from about 4:1 to about 167:1, otoprotective agent:platinum-coordination compound.

24. (Original) The method of claim 1, wherein the molar ratio of the effective amount of said otoprotective agent to the effective amount of said anti-tumor platinum-coordination compound is from about 4.25:1 to about 100:1, otoprotective agent:platinum-coordination compound.

25. (Original) The method of claim 1, wherein the molar ratio of the effective amount of said otoprotective agent to the effective amount of said anti-tumor platinum-coordination compound is from about 4.68:1 to about 20:1, otoprotective agent:platinum-coordination compound.

26. (Original) The method of claim 1, wherein the molar ratio of the effective amount of said otoprotective agent to the effective amount of said anti-tumor platinum-coordination compound is about 18.75:1, otoprotective agent:platinum-coordination compound.

27. (Original) The method of claim 1, further comprising administering to said patient a supplemental amount of said otoprotective agent during and/or after the course of treatment with said anti-tumor platinum-coordination compound.

28. (Original) The method of claim 27, wherein the supplemental amount of said otoprotective agent is administered orally, parenterally, or topically.

29. (Original) The method of claim 28, wherein the administration of said supplemental amount of said otoprotective agent is sufficient to maintain an effective blood serum level of the otoprotective agent in said patient for a period of from one to fourteen days during and/or after the administration of said anti-tumor platinum-coordination compound

30. (Original) The method of claim 29, wherein the administration of said supplemental amount of said otoprotective agent results in a blood serum level equivalent to that achieved by parenteral administration in the range of from about 0.1 mg/kg body weight to about 500 mg/kg body weight per week during and/or after the course of treatment with said anti-tumor platinum-coordination compound.

31. (Previously Presented) A method for reducing ototoxicity in a patient selected from the group consisting of a human, a cat, and a dog undergoing treatment with a chemotherapeutic effective amount of an anti-tumor platinum-coordination compound, the method comprising administering to said patient an effective amount of an otoprotective agent comprising L-methionine, D,L-methionine or a pharmaceutically acceptable salt thereof, the administration of said effective amount of said otoprotective agent resulting in a blood serum level equivalent to that achieved by parenteral administration in the range of from about 1 mg/kg body weight to about 100 mg/kg body weight.

32. (Previously Presented) The method of claim 31, further comprising administering to said patient a supplemental amount of said otoprotective agent, the administration of said supplemental amount resulting in a blood serum level equivalent to that achieved by parenteral administration in the range of from about 0.1 mg/kg body weight to about 500 mg/kg body weight per week.

Claims 33-45. (Canceled)

REMARKS

Claims 1, 3-5, and 7-32 are pending. Claims 33, 35-36 and 38-45 are canceled without prejudice and applicant reserves the right to present the claims in a continuation application.

35 U.S.C. § 112 Rejections

Reconsideration is respectfully requested of the rejection of claims 18-22 under 35 U.S.C. § 112, first paragraph as not satisfying the enablement requirement. Claim 18 is directed to a method for reducing the incidence of ototoxicity in a patient selected from the group consisting of a human, a cat, and a dog undergoing treatment with a chemotherapeutic effective amount of an anti-tumor platinum-coordination compound, the method comprising administering to said patient an effective amount of an otoprotective agent comprising methionine, the protective agent being administered parenterally, orally, or topically to the round window membrane. The claim has been amended to add a comma between "orally" and "or topically to the round window membrane" to make it clear that the phrase "to the round window membrane" modifies topically only and does not modify parenterally or orally. Thus, a person of ordinary skill would have known that the claim meant there were three methods of administration: (1) parenterally, (2) orally, and (3) topically to the round window membrane and claims 18-22 satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph.

35 U.S.C. § 102 Rejection

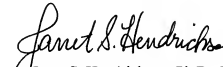
Reconsideration is respectfully requested of the rejection of claims 33, 35, 36, and 38-45 as being anticipated by Furuno et al. (U.S. Patent No. 3,962,429). Claims 33, 35, 36, and 38-45 are canceled and this rejection is moot.

CONCLUSION

Applicant submits that the present application is now in a condition for allowance and requests early allowance of the pending claims.

The Commissioner is hereby authorized to charge any under payment or credit any over payment to Deposit Account No. 19-1345.

Respectfully submitted,



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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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NOTICE OF ALLOWANCE AND FEE(S) DUE

321 7590 03/02/2009

SENNIGER POWERS LLP
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17TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
ANDERSON, JAMES D	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/02/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,448	10/27/2003	Kathleen C.M. Campbell	SIU 7398	8896

TITLE OF INVENTION: THERAPEUTIC USE OF METHIONINE TO REDUCE THE TOXICITY OF PLATINUM-CONTAINING ANTI-TUMOR COMPOUNDS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	06/02/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

321 7590 03/02/2009

SENNIGER POWERS LLP
100 NORTH BROADWAY
17TH FLOOR
ST LOUIS, MO 63102

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,448	10/27/2003	Kathleen C.M. Campbell	SIU 7398	8896

TITLE OF INVENTION: THERAPEUTIC USE OF METHIONINE TO REDUCE THE TOXICITY OF PLATINUM-CONTAINING ANTI-TUMOR COMPOUNDS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	06/02/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
ANDERSON, JAMES D	1614	514-562000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☐ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

☐ A check is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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321 7590 03/02/2009

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100 NORTH BROADWAY
17TH FLOOR
ST LOUIS, MO 63102

EXAMINER	
ANDERSON, JAMES D	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/02/2009

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/694,448	CAMPBELL, KATHLEEN C.M.	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Amendments filed 1/11/2009*.

2. ☒ The allowed claim(s) is/are *1,4,5 and 7-32*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)
1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/James D Anderson/ Examiner, Art Unit 1614	/Ardin Marschel/ Supervisory Patent Examiner, Art Unit 1614

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Janet Hendrickson on 2/17/2009.

Claim Amendments:

In claim 1, delete the words "the incidence of" in line 1.

In claim 1, insert the words ---in need thereof--- after "patient" in line 1.

In claim 1, delete the words "comprising methionine having the structure" in line 5 and insert therefore ---selected from the group consisting of L-methionine and a mixture of D-methionine and L-methionine---.

In claim 1, delete the chemical structure following the word "structure" in line 5.

In claim 1, delete the word "salt" in the last line and insert therefore ---salts---.

Cancel claim 3.

In claim 4, delete the word "comprises" and insert therefore the word ---is--- in line 2.

In claim 5, delete the word "comprises" and insert therefore the word ---is--- in line 2.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614